



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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. TO: The File

FROM: Director, Congressional Affairs Staff I
Office of Legislation

SUBJECT: Memorandum of Meeting, Wednesday, October 20, 1999
3:00 - 3:45PM, Room 120, Russell Senate Office
Building.

PARTICIPANTS:

FOOD AND DRUG ADMINISTRATION

Dr. Morris Potter, Deputy Director, CFSAN
Gerad McCowin, Deputy Director, Office of Food Labeling
Felicia Satchell, Chief, Food Standards Branch, Office of
Food Labeling
Geraldine June, Office of Food Labeling
Stephanie Smith, Office of Plant and Dairy Foods, and
Beverages
Michael Eck, Director, Congressional Affairs Staff I, Office
of Legislation

CONGRESSIONAL

Jill Hershey, Office of Senator Rick Santorum
Kevin Mathis, Office of Senator Arlen Specter
Jennifer Saraceno, Office of Representative Tim Holden

PENNSYLVANIA STATE OFFICIALS

Christian Herr, Pennsylvania Department of Agriculture
Sean Taylor, Washington Representative, Governor's Office

PENNSYLVANIA EGG INDUSTRY

Al Wenger, Agricultural Coalition of Pennsylvania
Jim Shirk, Assistant Vice President, Poultry Council; member of
The Penn Ag Industries Council
Dr. Dave Kradle, consultant to Penn Ag Industries

The meeting was requested by the offices of Senators Santorum and Specter and Representative Holden to give the Pennsylvania State Officials and the Pennsylvania egg industry another opportunity to present their views to the Food and Drug Administration of the efficacy of the Pennsylvania egg program and why safe handling labeling is not necessary for these eggs.

Ms. Hershey opened the meeting, thanking the FDA attendees for coming to listen about the Pennsylvania Egg Quality Assurance

96P-0418

MMI

Program (PEQAP). Mr. Wenger stated that the State government provides \$ 600 to \$ 1 million annually for the PEQAP, and 90 percent of the State's industry participate. He said safe handling labels make sense but that warning labels do not make sense for participants in the program because warning labels would remove the incentive for a producer to go to the extra cost and effort to participate in the program. PEQAP members view their products as a foodstuff, not a commodity.

Mr. Herr said he expects the Pennsylvania legislature to recommend that PEQAP be used nationwide. Since implementation of the PEQAP, SE incidence has dropped 50 percent in the midAtlantic states. They recommend a dual label, one for producers not in the program and a different label for producers that meet the PEQAP standards. Mr. Mathis expressed interest in a compromise that would incorporate the Pennsylvania standards.

Mr. McCowin said that FDA had received over 740 comments on the egg proposal, about 700 dealing with forced molting, two with refrigeration, a few with the enforcement approach, embargo, and seizure proposal, need for state involvement, and about 15 dealing with a range of labeling issues. He said the rule was one of CFSAN's high priority rules for calendar year 1999 and that he expected it would be on the "A list" for completion in 2000.

FDA officials were given the following items (attached) on the PEQAP:

Summary of a report entitled "A Five Year (1994-1999) Critical Analysis of the Pennsylvania Egg Quality Assurance Program (PEQAP), by David J. Henzler, Marlin Henninger and Phil DeBok, Commonwealth of Pennsylvania, Department of Agriculture, presented at the 1999 American Veterinary Medical Association/American Association of Avian Pathologist Annual Meetings, New Orleans, Louisiana, July 10-14, 1999." Poultry Poster #45.

The General Assembly of Pennsylvania, House Resolution No. 235, Session of 1999, "Memorializing Congress to recognize the Pennsylvania Egg Quality Assurance Program for its exceptional merit as a food safety program and to consider the program as the national standard."

A chart entitled "Comparison of PEQAP and other Programs."

Brochure entitled "Pennsylvania Egg Quality Assurance Program" revised January 1999.


Michael Eck

Attachments

Page 3

cc: Dockets Management Branch
(Docket No. 98N-1230)

A Five Year (1994 – 1999) Critical Analysis of the Pennsylvania Egg Quality Assurance Program (PEQAP)

David J. Henzler, Marlin Henninger and Phil DeBok

Commonwealth of Pennsylvania, Department of Agriculture, 230 1 North Cameron Street, **Harrisburg**, PA 1711 O-9408

SUMMARY. PEQAP is a voluntary *Salmonella enteritidis* risk reduction program in which 1,107 commercial layer flocks have been monitored in five years and two months (February 1994 to April 28, 1999). PEQAP is a cooperative program between the Pennsylvania Poultry Council (**PennAg** Industries Association), the Pennsylvania Department of Agriculture; the University of Pennsylvania (New **Bolton** Center), Penn State University, and the Pennsylvania Department of Health. The program includes risk reducing management practices, multiple-environmental and egg testing, a computerized database, and third party monitoring by the Pennsylvania Department of Agriculture. Overall 154 flocks (13.9%) had *S. enteritidis* positive environments. In single houses, 44 (9.8%) flocks, and in complexes, 110 (16.7%) flocks had *S. enteritidis* isolated from the environment. A comparison of flocks in houses monitored early in the program (1994) with flocks in the same houses in (1999), demonstrated a reduction in *S. enteritidis* environmental positivity from 25.7 % (18 of 70 flocks) to 7.3% (4 of 55 flocks). The number of environmental samples within these positive flocks also dropped from 35.8% (68 of 190) to 21.7% (10 of 46) from 1994 to 1999, respectively. Flocks housed in multiple house complexes were more likely to become exposed to *S. enteritidis* early after housing in the layer house. In total, 83 flocks (75.5%) had their 30 week environmental test positive as compared to flocks in single stand alone houses where 18 flocks (40.9%) had their 30 week test positive. A total of 933,900 eggs were cultured for *Salmonella enteritidis* and 146 positive eggs were isolated from 154 flocks. The overall prevalence of *S. enteritidis*- contaminated eggs from these environmentally positive flocks was 1.6 eggs/10,000 eggs produced. The number of contaminated eggs from flocks with *S. enteritidis* positive environments was higher in single stand alone houses versus complex houses with a prevalence of 2.0 eggs/10,000 eggs produced, compared to 1.4 eggs/10,000 produced, respectively. It has been estimated that greater than 70% of the cases of food borne illness due to *Salmonella enteritidis* are associated with the consumption of foods containing eggs. Between 1989 and 1997 there was a 50.0%, 48.6%, 55.4%, and 43.5% reduction in human *S. enteritidis* isolation rates per 100,000 population for the States of Pennsylvania, Maryland, New Jersey, and New York, respectively. Pennsylvania is the principal supplier of eggs to these States. PEQAP likely contributed to this combined 49.4% reduction of human *S. enteritidis* rates in the mid-Atlantic States.

Presented at: 1999 American Veterinary Medical Association/American Association of Avian Pathologist Annual Meetings, New Orleans, Louisiana, July 10- 14, 1999. @ Poultry Poster #45.

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 235 Session of
1999

INTRODUCED BY CAPPABIANCA, BUNT, GORDNER, WALKO, CALTAGIRONE,
LAUGHLIN, READSHAW, GRUCELA, SOLOBAY, BELARDI, LESCOVITZ,
SHANER, M. COHEN, PISTELLA, TIGUE, TRELLO, MCCALL, STABACK,
YOUNGBLOOD, HENNESSEY, DeWEESE, HALUSKA, COLAFELLA, DeLUCA,
STERN, SCHULER, TRAVAGLIO, B. SMITH, E. Z. TAYLOR, HERSHEY,
BEBKO-JONES, ROONEY, GEIST, WILLIAMS, SURRA, EVANS,
WOJNAROSKI, SATHER, VAN HORNE, SEYFERT, PESCI, S. MILLER,
CORRIGAN, LUCYK, LEDERER, KIRKLAND, HARHAI AND PIPPY,
SEPTEMBER 20, 1999

REFERRED TO COMMITTEE ON INTERGOVERNMENTAL AFFAIRS,
SEPTEMBER 20, 1999

A CONCURRENT RESOLUTION

1 Memorializing Congress to recognize the Pennsylvania Egg Quality
2 Assurance Program for its exceptional merit as a food safety
3 program and to consider the program as the national standard.

4 WHEREAS, This Commonwealth is the fifth largest egg producing
5 state in the country and has led the way in food safety for
6 almost ten years and now stands at the forefront of national
7 standards; and

8 WHEREAS, This Commonwealth supplies almost the entire Mid-
9 Atlantic region with their table eggs; and

10 WHEREAS, The Pennsylvania Egg Quality Assurance Program
11 (PEQAP) is a voluntary program developed by the egg industry and
12 administered by the Penn Ag Poultry Council, a nonprofit
13 agricultural trade association; and

14 WHEREAS, The program utilizes risk-reducing management

1 practices, such as third-party monitoring and egg testing, to
2 successfully improve the safety of this product; and

3 WHEREAS, Laboratory testing of eggs and environmental samples
4 are completed by the Certified Pennsylvania Animal Diagnostic
5 Laboratories at The Pennsylvania State University, the
6 University of Pennsylvania at New Bolton Center and the
7 Department of Agriculture; and

8 WHEREAS, The program utilizes safe handling labels versus
9 warning labels, which often leave a negative connotation; and

10 WHEREAS, The guidelines under the program cover egg
11 production and assure the commitment of the producer and
12 processor to implement the best management and monitoring
13 practices most likely to prevent Salmonella enteritidis
14 contamination; and

15 WHEREAS, Annually the egg industry invests over \$1,000,000 in
16 the program on implementation, promotion and public awareness;
17 **and**

18 WHEREAS, According to a recent analysis of the program
19 completed by the Department of Agriculture there was a 49.5%
20 reduction in human Salmonella enteritidis isolation rates in the
21 Mid-Atlantic region where this Commonwealth is the principal egg
22 supplier; and

2 3 WHEREAS, According to a 15-member review team report prepared
24 by the Food and Drug Administration, Centers for Disease Control
25 and Prevention and United States Department of Agriculture,
26 dated January 18, 1997, it was stated that PEQAP can serve as a
27 prototype for the egg industry in the development of egg quality
28 assurance programs and that the industry should adopt quality
2 9 assurance programs based on interventions developed in the
30 Pennsylvania Pilot **Project and used in the Pennsylvania Egg**

1 Quality Assurance Program; therefore be it

2 RESOLVED (the Senate concurring), That the General Assembly.

3 of the Commonwealth of Pennsylvania memorialize the Congress of
4 the United States to recognize the merit and effectiveness of
5 the Pennsylvania Egg Quality Assurance Program and to allow any
6 state that follows these protocols to use a safe handling label
7 which emphasizes refrigeration and proper cooking; and be it
8 further

9 RESOLVED, That the General Assembly memorialize Congress to
10 recognize the thorough and effective standards of the program
11 and consider adopting the program as the national standard,
12 thereby requiring no additional labels on eggs produced under
13 the program protocols; and be it further

14 RESOLVED, That copies of this resolution be transmitted to
15 the presiding officers of each house of Congress and to each
16 member of Congress from Pennsylvania.

Comparison of PE, QAP and other programs



	P E Q A P	MD	NY	N.E.	OH	SC	UEP	CA
Chick Testing								
From NPIP "U.S. SE monitored" breeders	✓	✓	✓	✓	✓	✓	✓	✓
Chick paper (meconium) testing - 10% of papers	✓	✓	✓	✓				

Pullet/Layer Testing

Pullets - 15 weeks	✓	✓	✓	✓				
Layers - 7-10 days if not tested as pullets	✓	✓						
- 30 weeks	✓	✓						
- 45 weeks	✓	✓						
- Molted (post molt)	✓	✓						
- Spent fowl (just prior to depopulation)			✓	✓	✓	✓	✓	

Egg Testing/Diversion

4 tests of 480 eggs every 2 weeks, then monthly for life	✓	✓						
Positive eggs to pasteurization or hard cooked	✓	✓						

Management Requirements

Educational programs	✓	✓	✓	✓	✓	✓	✓	✓
Biosecurity	✓	✓	✓	✓	✓	✓	✓	✓
Rodent control	✓	✓	✓	✓	✓	✓	✓	✓
Environmental decontamination (C&D)	✓	✓	✓	✓	✓	✓	✓	✓
Third party monitoring (state government)	✓	✓	✓					✓
Data with centralized records (chicks to spent fowl)	✓							

Processing Plant Requirements

Specified procedures with documentation	✓	✓	✓					✓
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* Note: New England Risk Reduction program has an option that includes testing during production cycle and egg testing.

Program Requirements

PULLETS


- Purchase chicks from U.S. Sanitation Monitored *Salmonella enteritidis* negative breeder flocks.
- Obtain samples of chick dropping papers at time of delivery. Sample every 10th chick paper and submit to laboratory for *Salmonella enteritidis* (SE) culture.
- Sample and culture the manure at 10 to 15 weeks of age. A culture will consist of two samples taken from the manure beneath each row of cages.
- Maintain a defined rodent control and monitoring program.
- Houses with positive manure or chick samples must be cleaned and disinfected before new chicks can be placed.

LAYERS

- Purchase and place pullets from an SE monitored flock. Pullets from an unknown or SE positive status house or flock will require that the manure be sampled and cultured 7 to 14 days after placement.
- Sample and culture manure at 29 to 31 weeks of age and again at 44 to 46 weeks of age. A culture of the manure during any test will consist of two samples taken from the manure beneath each row of cages.
- In molted flocks test manure at five to seven weeks following return to feed and follow egg testing procedures if positive.
- Houses with positive manure samples must be thoroughly cleaned and disinfected between flocks.

EGGS

- Houses with negative manure samples will not be required to test eggs.

- Houses with positive manure samples must test 480 nest run eggs or a combination of all available blood spot eggs plus additional nest run eggs to total 480 eggs every 2 weeks for 4 lots of samples. These eggs will be cultured in pools of 20. If the 4 lots of eggs are negative, a sample of 480 eggs (nest run and blood spot) must be sampled each month for the life of the flock.
- If any egg pools are positive, then all eggs must be diverted for pasteurization or hard cooking. To be able to resume sale of eggs as table eggs,  eggs must be tested in pools of 20 every 2 weeks for 4 lots of samples and test negative. Alternatively, if less than 50% of the environmentals and no more than one egg pool were positive, 4,000 eggs may be tested at one time. Following return to the table egg market, 480 eggs (nest run and blood spot) must be sampled each month for the life of the flock.
- Egg testing will eliminate the need for further environmental rating.
- As additional experience is gained, environmental and egg testing requirements may be modified.

FORCE MOLTED FLOCKS

- Test manure at five to seven weeks following return to feed and follow egg testing procedures if positive.

RODENT CONTROL

- A defined rodent control, and record monitoring program must be maintained at all times.

BIO-SECURITY

- All participants must maintain an acceptable biosecurity program.

REFRIGERATION

- Eggs must be kept under refrigeration as specified in the Pennsylvania law.

Processing Plant

- Processing plants packing eggs bearing the PEQAP "Tested Quality" Seal must meet all applicable USDA, Pennsylvania Department of Agriculture, and PEQAP program requirements. These address plant and employee sanitation, refrigeration, egg washing and sanitation, water testing, packing materials, carton coding and records.

Participating producers and processors are:

- demonstrating their concern about food safety
- producing a quality egg which helps to assure consumer confidence in eggs.
- addressing the demands of buyers for eggs produced in a food safety program.
- reducing potential foodborne illness liability claims.
- may have insurance premiums reduced

What Regulatory Officials Say

In a 15 member Review Team Report by the Food and Drug Administration, Centers for Disease Control and Prevention and USDA dated January 18, 1997 it was stated: "PEQAP can serve as a prototype for the egg industry in the development of egg quality assurance programs and the industry should adopt quality assurance programs based on interventions developed in the Pennsylvania Pilot Project and used in the Pennsylvania Egg Quality Assurance Program (PEQAP).

Statement of Purpose

The Pennsylvania Egg Quality Assurance Program (PEQAP) is a voluntary industry program intended to minimize *Salmonella enteritidis* (SE) contamination of chicken (shell) eggs. Although this program does not guarantee shell eggs to be free of SE contamination, the program does assure commitment of the producer and processor to implementation of those management and monitoring practices most likely to prevent SE contamination. Basic preventive measures include placement of SE clean chicks, intensive rodent control, cleaning and disinfecting between flocks, and environmental monitoring of pullet and layer houses with continuous testing of eggs from any environmentally positive houses. Positive eggs are diverted for pasteurization. Eggs must be kept refrigerated. The Pennsylvania Department of Agriculture provides oversight, technical, administrative, and financial support to this program. The Pennsylvania Department of Health provides technical advice regarding public health implications. PEQAP participants are assuring the public that they are taking every reasonable precaution to assure the safety of shell eggs.

SPONSORED BY:

PennAg Industries Poultry Council

SUPPORTED BY:

*Pennsylvania Department of Agriculture
Penn State University
University of Pennsylvania
Pennsylvania Animal Health Commission
Pennsylvania Department of Health*

PennAg Industries Poultry Council

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PEQAP

MONITORED BY THE PA DEPARTMENT OF AGRICULTURE

Pennsylvania Egg Quality Assurance Program



PEQAP

MONITORED BY:

Pennsylvania Department of Agriculture

***Egg Quality and Safety
from Farm to Market***

Revised January 1999

CROSS FILE SHEET

File Number:

98N-1230/ *MMI*

See File Number:

97P-0197/ *MMI*

96P-0418/ *MMI*